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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/652,676

08/28/2003

Joseph Utermohlen

191/001/DIV1

2546

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VENTANA MEDICAL SYSTEMS, INC.
ATTENTION: LEGAL DEPARTMENT
1910 INNOVATION PARK DRIVE
TUCSON, AZ 85755

EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

08/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/652,676	Applicant(s) UTERMOHLEN ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-14 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-14 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 5/21/07 to the Office action has been entered. Claims 9-14 and 18-21 are pending.

1. Applicant's arguments with respect to claims 9-14 and 18 have been considered but are moot in view of the new ground(s) of rejection.

NEW GROUND OF REJECTIONS NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 112

2. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Since the phrase "optionally" in claim 21 has no support in the specification, it constitutes a new matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 9-14 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (4,886,741, issued December 12, 1989).

Schwartz et al. disclose using volume exclusion agents to enhance in situ hybridization rates between short oligonucleotide probe and their target polynucleotides where the cells containing the target polynucleotide are adhered onto a glass substrate (See the Abstract, column 2, lines 30-35). The volume exclusion agent is at a concentration of 2% to 25% (w/v) of the reaction mixture (column 2, lines 48-53). One of the volume exclusion agents is dextran sulfate (See column 3, lines 1-3, column 6, lines 31-33, and column 10, lines 25-26). The preferred polymer weight is at least 10,000 daltons (See column 3, lines 14-15). The tissues are prepared by freezing, perfusion and embedding with paraffin prior to sectioning (See column 3, lines 67-68). The probe is labeled with fluorophores (See column 5, lines 24-25).

Schwartz et al. do not disclose that an automated staining system having evaporation inhibitor liquid covering a polynucleotide hybridization buffer-covered target on the slide is used.

However, an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art (See MPEP, 2144.04, III) The statement is cited as follows:

In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (Appellant argued that claims to a permanent mold casting apparatus for molding trunk pistons were

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allowable over the prior art because the claimed invention combined “old permanent-mold structures together with a timer and solenoid which automatically actuates the known pressure valve system to release the inner core after a predetermined time has elapsed.” The court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.).

Schwartz does not disclose the exact molecular weight of dextran sulfate.

It would further have been prima facie obvious to perform routine optimization using reagents, as noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection specific molecular weight of dextran sulfate was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

4. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (4,886,741, issued December 12, 1989) as applied to claims 9-14 and 19-21 above, and further in view of Towne et al. (6,855,552, issued February 15, 2005).

The teachings of Schwartz are set forth in section 3 above. Schwartz does not disclose that the probe composition is arrayed on a solid substrate.

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Towne et al. disclose automated immunohistochemical and in situ hybridization assay (See the Abstract and column 4, lines 49-63). The method of Towne et al. comprises automatic hybridization, removal and detection steps (see entire document). Towne et al. also disclose that biological sample includes tissue arrays (See column 14, lines 8-14). This teaching suggests that after hybridization on a target, the probe composition is arrayed on a solid substrate.

One of ordinary skill in the art would have been motivated to apply the tissue array of Towne et al. to the method of Schwartz because it increases the accessibility of various molecules to their respective targets and to improve tissue and cell readability of biological sample on automated instruments (See column 1, lines 26-32). It would have been prima facie obvious to apply the probe composition, which is arrayed on a solid substrate.

Summary

5. No claims are allowable.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

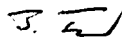
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung 
July 24, 2007


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